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(HL)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/7876,812	06/17/97	DOUGLAS	T 11879

HM12/0609

PHAN, Q EXAMINER

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ART UNIT	PAPER NUMBER
1541	10

06/09/97

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. <b>08/876,812</b>	Applicant(s) <b>Douglas et al</b>
Examiner <b>Quang N. Phan</b>	Group Art Unit <b>1641</b>

Responsive to communication(s) filed on Mar 1, 1999

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 1-51 is/are pending in the application.

Of the above, claim(s) 17-51 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-16 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

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### **DETAILED ACTION**

1. Applicants' election without traverse of Group I in Paper No. 7 is acknowledged.

The restriction of Group II and Group III as indicated in Paper No. 7 is proper. Claims 17-51 withdrawn from further consideration by the examiner, 37 CFR 1.142 (b), as being drawn to a nonelected invention.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1, lines 6 and 9, should recite --having a first-- and --having a second-- respectively.

Claims 11 and 12, should recite --The electrochemical test device-- for consistency.

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold et al (US Pat. No. 5,437,999) as applied to claims 1-16 above, and further in view of Ovahinsky et al (US Pat. No. 4,217,374).

Diebold et al disclose the invention substantially as claimed. Specifically, Diebold disclose a high-resolution electrodes for use in an electrochemical sensor. A working, counter, or reference electrode element is produced in accordance with the invention have highly defined and reproducible size and shape, and importantly have a precisely-defined working electrode area. Fabricating an electrode in accordance with the inventions involves first attaching a high quality thin metal film (e.g., polyimide or other polymer such as polyester, polyethylene terephthalate (PET), or polycarbonate) to a bare rigid or flexible substrate. A layer of photoresist is then applied to the thin metal layer and patterned using photolithography to precisely define an electrode area and contact pad. In the case of a reference or counter electrode, the metal may be applied directly to a standard printed circuits boards (PCB). The material use in a reference electrode is silver/silver chloride. The resulting metallized substrate displays extremely small and uniform grains, and importantly does not contain copper or others electrochemically active materials. Such surfaces are nearly ideal for the purpose of making electrochemical measurements in biological or corrosive solutions. A second insulating substrate is then applied to the metal layer and precisely patterned to form an open electrode area and a meter contact pad. As a result of the photolithographic process described, first cutout portion and second cutout portion are formed in second insulating substrate exposing the underlying metallized thin support

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material. In finished electrode element, the area of first cutout portion defines the electrode area and second cutout portion acts as a contact pad between source. In addition, vent port which extends through the substrates in the finished electrochemical sensor as a means of introducing the sample to the capillary space. Many different types of reagent may be applied to the working electrode and/or the reference or counter electrode to provide for a fully functional sensor whose signal is selective for and sensitive to the concentration of an analyte (e.g., glucose). The reagent should include at least a mediator (potassium ferricyanide) and an enzyme (glucose oxidase). ( See Abstract, col. 3, 4, 10, 12, and Table I).

Diebold et al fail to teach an amorphous semiconductor material affixed to the electrode.

Ovshinsky et al teach the formation of an amorphous semiconductor to be deposited on a substrate. Amorphous semiconductor materials are zinc, gold, copper, silver, manganese. And alkaline atoms such as lithium or sodium is added to amorphous silicon film to create new states in the energy gap of the film. The amorphous semiconductor materials can act like crystalline materials and be useful in devices, such as solar cells and current controlling devices, including p-n junction devices, diodes, transistors and the like. (See col. 7,12, and claims).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the amorphous semiconductor material affixed to the electrodes taught by Diebold et al in a electrochemical test device wherein the amorphous semiconductor film provided an increase conductivity in ohmic interfaces. One of ordinary skill in the art at the time the invention was made would have been motivated to modified the

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electrochemical device by the addition of conduction-increasing materials so that the conductivity is increased.

***Conclusion***

5. No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang N. Phan whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Thursday from 7:30 am to 5:00pm. The examiner can also be reached on alternate Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

QNP

May 24, 1999

*James C. Housel*  
JAMES C. HOUSEL  
SUPERVISORY PATENT EXAMINER  
6/7/99